201-14484

NCIC HPV
Sent by: Mary-Beth Weaver

05/22/2003 01:23 PM

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Subject: Environmental Defense comments on 2,4,6-Tribromophenol (CAS# 118-79-6)

Richard_Denison@environmentaldefense.org on 05/20/2003 12:56:19 PM

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Subject: Environmental Defense comments on 2,4,6-Tribromophenol (CAS# 118-79-6)

(Submitted via Internet 5/20/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and rhenrich@glcc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 2,4,6-Tribromophenol (CAS# 118-79-6).

Great Lakes Chemical Corporation has submitted a Robust Summary/Test Plan for 2,4,6-tribromophenol in response to the EPA High Production Volume Challenge. On review of Test Plan we find that it provides the minimum information required to address most of the requested SIDS elements. It also provides essentially no information regarding production, use, distribution and possible sources of human and environmental exposure to this chemical. For example, the Test Plan only briefly mentions that 2,4,6-tribromophenol is used as a flame retardant, and fails to mention the products in which it is so used. It also fails to mention that this chemical has been or is currently used as an antiseptic and as a chemical intermediate. Significantly more information is available on this compound than is provided. (See, for example, the National Toxicology Program web site for this chemical: http://ntp-server.niehs.nih.gov/htdocs/CHEM_H&S/NTP Chem1/Radian118-79-6.html.

Evidence presented in the Robust Summary/Test Plan indicates that 2,4,6-tribromophenol is not degraded by microorganisms and that it bioaccumulates in mammals and fish. Thus, it would be expected to accumulate and persist in the environment and to be magnified in the upper levels of the food chain. However, there is no discussion of possible sources of environmental exposure or measures that are or might be taken to prevent the release of this chemical into the environment. While not strictly required under the program, we feel that for chemicals with these characteristics, such discussions are critical information and should be included in the Test Plan.

No references are cited in the Test plan. Further, on review of the Robust Summary we note that virtually all the references cited are confidential company reports and, as such, are not available to the public. Our brief search of the literature turned up 176 reports on this chemical in the open literature. While we are aware that not all of these reports address the requested SIDS elements, many do. It is our opinion that, whenever possible, data cited to address the SIDS elements should be available to the public.

Other Comments:

1. A chemical structure for 2,4,6-tribromophenol is not provided.

2. Physical Chemistry: The literature indicates 2,4,6-tribromophenol is significantly more water soluble, 1-10 g/L, than indicated in this table.

3. Mammalian Toxicity: We realize that LD50 data can be notoriously inaccurate. However, data cited by the National Toxicology Program indicates a much lower LD50, 200 mg/kg, than those cited here. Further, one source cited in the Robust Summary states that all animals receiving an oral dose of 5,000 mg/kg died, whereas another indicates an oral LD50 of 5012 mg/kg. (Both of these studies are judged to be reliable.) This disparity in these data is so great that the quality of the respective references should be considered and discussed, and the best data indicated.

4. The sponsor argues under Reproductive Toxicity that: "The data from the repeated dose studies showed no adverse effects on the ovaries, testis, prostrate or uterus. The data contained in the teratology and developmental neurotoxicity study showed developmental and neurotoxic effects at several dose levels. Based on the hazard information already available and the fact that tribromophenol is used as a rate limited intermediate and is incorporated into resin or plastics, it is believed that enough data already exists to assess the mammalian toxicity of the chemical. Therefore it is not necessary to fill this screening level endpoint."

We disagree for several reasons. First, the sponsor's claim that tribromophenol is a rate-limited intermediate is not supported by any data provided either in the test plan or robust summary, and at any rate is not equivalent to being a closed-system intermediate (for which an exemption from reproductive toxicity testing would apply). Second, even if one of the chemical is a rate limited intermediate, the fact that this chemical is also incorporated into resin and plastics clearly rules out any exemption, and, indeed, could well be a significant source of environmental exposure; nothing provided in the sponsor's submissions addresses this question. Third, the sponsor's claim that the repeated dose studies showed no adverse effects on reproductive organs is unsupported; the robust summaries of the repeated dose studies do not mention any examination of reproductive organs or the findings of such examinations. Unless the sponsor can provide studies documenting this claim, reproductive toxicity testing is required to fulfill the requirements of the HPV Challenge Program

For all of these reasons, we also must challenge the sponsor's indication in its Test Plan Matrix that this SIDS element has been completed.

5. We did not see evidence to support exclusive use of this chemical as a flame retardant in resins and plastics. The NTP report indicates other uses.

6. No mention is made regarding the fate of 2,4,6-tribromophenol when the resin or plastic containing it degrades.

In summary, for reasons cited above, we find the Robust Summary/Test Plan submitted for 2,4,6-tribromophenol does not adequately address the requirements of the EPA High Production Volume Challenge Program.

Thank you for this opportunity to comment.

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